Vermont Health Access
Pharmacy Benefit Management Program
DUR Board Meeting Minutes: 06/12/07

Board Members:

Michael Scovner, M.D., Chair
Andrew Miller, R. Ph.
Kathleen Boland, Pharm.D.
Frank Landry, M.D.
Rich Harvie, R.Ph.
Norman Ward, M.D.
Cheryl Gibson, M.D.
Lynne Vezina, R.Ph.
Stuart Graves, M.D.
Virginia Hood, M.D.

Staff:

Ann Rugg, OVHA
Diane Neal, R.Ph., (MHP)
Jennifer Mullikin, OVHA
Scott Strenio, M.D., OVHA
Nancy Miner, (MHP)
Sandi Drury, (MHP)
Clark Eaton, OVHA
Robin Farnsworth, OVHA
Stacey Baker, OVHA

Guests:

Andrea Hayes, Sanofi-Aventis
Bob McSparren, BMS
Carl Marchand, AstraZeneca
Carl Pepe, GSK
Chuck Burnett, Sanofi-Aventis
David Anderson, AstraZeneca
Doug Kenyon, MedImmune
Ellen Flatley, GSK
Gordon Gendron, J&J
James Kokoszyna, Allergan
Jenifer Buttle, Merck
Judy Kando, OMJ
Keith White, Genentech
Leslie Mason, Alcon
Lyndon Braun, Santarus
Maribeth Klettke, Sanofi-Aventis
Mark Kaplan, Abbott
Mary Kaysen, Takeda
Matt Badalucco, Merck
Michael McNamara, D.O.
Mike DeOrsey, Abbott
Molly Miller, OMJ
Paul Amato, GSK
Paul Fanikos, BIPI
Paul Kelly, Janssen
Scott Mosher, GSK
Sharon Satterfield, M.D.
Stephanie Parker, Wyeth
Tom Madson, Eli Lilly

Michael Scovner, M.D., Chair, called the meeting to order at 7:00 p.m. at the DUR Board meeting site in Williston.

1. Executive Session:

- An executive session was held from 6:30 until 7:00 p.m. to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2).

2. Introductions and Approval of DUR Board Minutes:

- Introductions were made around the table.
- The May 2007 meeting minutes were accepted as printed without amendment.

Public Comment: No public comment.

3. OVHA Pharmacy Administration Updates: *Ann Rugg - Deputy Director, OVHA*

- Proposed Summer Break: This June agenda is extensive as it is proposed that the DUR Board not meet during the months of July and August.
- S115 – Privacy Provision for Prescribing: This bill was passed in the legislature. The bill has a provision to protect prescribing information from disclosure. Other components of the bill include:
  a. A modest expansion of the Healthy Vermonters' program to include an increase in income from 300% to 350% of poverty.
  b. An evidence based education program.
  c. A generic drug voucher program as an alternative to samples of expensive brand name drugs.
  d. A purchasing consortium for State only programs.
- Disclosure Policy for DUR Board Members: All Board members were asked to complete the disclosure form included in the DUR packet and return it to OVHA. This form will be completed annually.

4. Medical Director Update: *Scott Strenio, M.D. – Medical Director, OVHA*

- Physician Comments: Included in the DUR packet for review by the Board, including comments regarding Lyrica®.
- Clinical Programs Update: OVHA is continuing its care coordination initiative and the chronic care management vendor chosen by OVHA is scheduled to start work this summer.
- Methadone FDA Alert: The FDA methadone alert was discussed with Dr. Michael Borrello from the FAHC Pain Clinic. Dr. Borrello stated that the concerns with methadone are torsades and risk of overdose and respiratory depression when converting from other narcotic analgesics. Dr. Borrello suggested that the 40 mg dispersable tablet require prior authorization when there is no recent prescription history of methadone use so that prescribers would be encouraged to start with low doses.

5. Follow-up items from Previous Meeting: *Diane Neal, R.Ph., MedMetrics Health Partners (MHP)*

- Methadone
  (See discussion above)

Public Comment: No public comment.

Board Decision: Methadone 40 mg dispersable tablets to require prior authorization if no recent claims history for methadone.

- Capital® with Codeine
  Dr. Richard Hubbell (Pediatric ENT) and Dr. William Brundage (Adult ENT) both responded via e-mail that generic acetaminophen with codeine oral liquid was well tolerated by patients and there was no need for specific criteria for the non-alcohol containing Capital® with Codeine.

Public Comment: No public comment.

Board Decision: None needed.

- Ophthalmics: Wetting Agents
  Deferred until next meeting as no feedback from an ophthalmologist who performs corneal transplants has been obtained.

6. Clinical Update: New Drug Reviews: *Diane Neal, R.Ph.(MHP)*

Note: All drug/criteria decisions will be reflected in the next PDL and/or Clinical Criteria update.

- Invega® (paliperidone) – Not recommended for addition to the PDL. Coverage would require PA with the criteria for approval as for other non-preferred atypical antipsychotic tablets (the patient has been started and stabilized on the medication (no samples) or the patient has had a documented side effect, allergy or treatment failure with at least two preferred products). A quantity limit of 1 tablet per day for the 3 mg and 9 mg tablets and 2 tablets per day for the 6 mg tablets was recommended. Ann Rugg, Deputy Director, OVHA, distributed utilization data that showed drug spend by therapeutic class that illustrated that the antipsychotic medication class is OVHA's most costly therapeutic drug class and that the preferred agents are widely used.

Public Comment: *Michael McNamara, D.O., North Country Hospital* – Commented on patient experience with Invega® and the advantages of extended release preparations.
Sharon Satterfield, M.D., VSH and Second Spring – Commented on patient experience with Invega® and the side effect profile.
Judy Kando, Ortho-McNeil Janssen – Commented on one year extension studies with Invega®.

Board Decision: The Board approved the MHP recommendations as described.

- Lyrica® (pregabalin) – Not recommended for addition to the PDL. Recommendations for criteria for coverage of Lyrica® for adjunctive therapy for partial seizure would include an appropriate diagnosis and require that the patient be receiving at least one other anticonvulsant (processed via automated step therapy). Recommendations for criteria for coverage of Lyrica for use in neuropathic pain associated with diabetic peripheral neuropathy or post herpetic neuralgia would include an appropriate diagnosis and a documented side effect, allergy, or treatment failure to a tricyclic antidepressant (TCA), generic gababentin, or another anticonvulsant (processed via automated step therapy). The recommended quantity limit is 3 tablets per day for all strengths.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above with the requested change that the automated look back edit for use of 2 prior drugs from the tricyclic antidepressant class and/or anticonvulsant class.

- Abilify® (aripiprazole) Injection for IM Use – Not recommended for addition to the PDL. Criteria for coverage would include medical necessity for an IM formulation and the patient has a documented side effect, allergy, or treatment failure to Geodon IM or clinically compelling rationale for the drug and dosage form is provided.

Public Comment: No public comment.

Board Decision: The Board approved the MHP recommendations noted above.

7. Review of Newly-Developed/Revised Clinical Coverage Criteria: *Diane Neal, R.Ph, (MHP)*

- Pulmonary: Antihistamines: 1st Generation:
  This category was presented as a new category. Second generation antihistamines have been a managed category for some time. Preferred single entity 1st generation antihistamines and antihistamine/decongestant combinations would be generic products with all branded single entity and combination antihistamine/decongestant products requiring prior authorization with the criteria for approval to be the provision of clinically compelling information to support the choice of a non-preferred agent.

Public Comment: No public comment.

Board Decision: The new category with the presented clinical criteria for non-preferred agents was unanimously accepted.

- Pulmonary: Antihistamines: 2nd Generation:
  The table had never included brand name Claritin® and Claritin D® so an updated table was presented.

Public Comment: No public comment.

Board Decision: The revised table was unanimously accepted.

- Rheumatoid & Psoriatic Arthritis Medications: Injectables:
  Previously called "Rheumatoid Arthritis Medications", this category was expanded to include psoriatic arthritis and Orencia® and Remicade® were added to the non-preferred agents after clinical criteria are met. The use of Orencia® and Remicade® will require prior authorization regardless of whether the claim is processed through the pharmacy or medical benefit. A PA form for rheumatoid and psoriatic arthritis injectable medications was presented.

Public Comment: No public comment.

Board Decision: The clinical criteria were accepted with the request that the first and second line therapies required before approval of these agents be more clearly outlined. The PA form was approved as presented.

- Ankylosing Spondylitis Medications: Injectables:
  This indication was not previously addressed in our managed categories although all the medications were listed in the PDL for other indications. It was recommended that Enbrel® and Humira® be listed as preferred agents after clinical criteria are met and Remicade® be listed as non-preferred after clinical criteria are met. A PA form for ankylosing spondylitis injectable medications was presented.

Public Comment: No public comment.

Board Decision: The Board approved the clinical criteria and drug placement as recommended. The PA form was also approved as presented.

- Psoriasis Medications: Injectables:
  The medications included in this category have not changed preferred status. Clinical criteria were modified to be easier to understand. An updated PA form was presented.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted. The PA form was also approved as presented.

- Ulcerative Colitis Medications: Injectables:
  This indication was not previously addressed in our managed categories although Remicade® was listed in the PDL for other indications. It was recommended that Remicade® be PA required and the patient to have failed a conventional treatment. A PA form for ulcerative colitis injectable medications was presented.

Public Comment: No public comment.

Board Decision: The clinical criteria were accepted as presented with the request to change the wording to require the patient to have failed at least two of the three listed conventional therapies. The PA form was approved as presented.

- Crohn's Disease Medications: Injectables:
  This indication was not previously addressed in our managed categories although all the medications were listed in the PDL for other indications. It was recommended that Humira® be listed as preferred after clinical criteria are met and Remicade® be listed as non-preferred after clinical criteria are met. A PA form for crohn's disease injectable medications was presented.

Public Comment: No public comment.

Board Decision: The clinical criteria were accepted as presented with the request to change the wording to require the patient to have failed at least two of the listed conventional therapies. The PA form was approved as presented.

- Synagis®:
  The only change recommended for the clinical criteria was to change the dates for approval to be in line with the RSV season in Vermont. It was recommended that Synagis® be administered between November 1st and April 30th (total maximum of 6 doses). It was recommended that Synagis® claims not be processed through the medical benefit (only available for payment through the pharmacy benefit) as had previously been decided, but coding needs to be blocked so claims reject if submitted through the medical benefit. It was also recommended that OVHA proceed with an RFP for provision of Synagis® (as had been approved by the legislature two years ago) via specialty pharmacy. Specialty pharmacy providers would provide additional services, such as follow-up reminders to families of scheduled doses and health coaching, in addition to provision of the drug.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted. The recommendation to solicit specialty pharmacy bids for provision of Synagis® and related services was also unanimously accepted.

- Antipsychotics: Atypical and Combination:
  The table of medications was divided up by dosage form. The clinical criteria were rewritten to make it clear how a patient would meet criteria for a PA required medication. Abilify® discmelt had never been addressed in the table and is now listed.

Public Comment: No public comment.

Board Decision: The revised clinical criteria and reformatted table were unanimously accepted.

- Antipsychotics: Typical:
  It was recommended that the clinical criteria be revised to read that for an approval of a PA required medication (all brand name products with generics available) the patient has had a documented side effect, allergy or treatment failure with at least two preferred products (one of which must be the generic formulation of the requested brand name product).

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

- Antidepressants: Novel:
  It was recommended that the clinical criteria be revised so that there will be an automated step therapy for the approval of Effexor® XR and venlafaxine IR. Claims history will be automatically reviewed for previous use of 2 different antidepressants from the SSRI and/or novel antidepressant categories, and if found, the prescriber will no longer need to contact the clinical call center via phone or fax. Standard SPMI language was also added to the category.

Public Comment: No public comment.

Board Decision: The revised clinical criteria were unanimously accepted.

8. New Drug Classes: *Diane Neal, R.Ph. (MHP)*

Note: All drug/criteria decisions from this section will be reflected in the **07/01/07** PDL and/or Clinical Criteria update unless specified otherwise.

- Botulinum Toxins:
  It was proposed that all botulinum toxin preparations (both Type A and Type B) be PA required. Clinical criteria for approval were presented. Cosmetic use will not be an approved use. It was recommended that the same clinical criteria be used when botulinum toxin claims are processed through the medical benefit.

Public Comment: James Kokoszyna, Allergan requested that the clinical criteria be modified to be specific for each toxin type.

Board Decision: The Board approved as recommended but requested that the clinical criteria be modified to be specific for each toxin type.

- Compounded Products: Bioidentical/Individualized Hormonal Products:
  Commercially available hormonal products for use during menopause are not contained within a managed drug class and so all commercial products in a variety of dosage forms, strengths, and combinations are available without prior authorization. Dr. Cheryl Gibson explained that compounded hormonal products are not tested nor regulated by the FDA and that there is no data to support the claim that these products are safer than conventional commercially available products. Several national groups (including the American College of OB'GYN) have weighed in on this issue and together have said there is no benefit in using these compounded hormonal products. It was recommended that compounded hormonal products not be a Vermont Medicaid benefit with the exception of natural micronized progesterone capsules which should be available for peanut allergic women only where the commercial product is formulated in peanut oil. There will be no grandfathering of current users.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

- Non-Managed Classes: Combination products, kits, unusual dosage forms:
  New drug products released on the market are reviewed every 2 weeks by MedMetrics Health Partners to determine pharmacy benefit coding according to the current PDL. There are a variety of products released on the market that are not in a drug class that is currently managed or that are not specifically addressed in the PDL. It was recommended that when new products are released that appear to be illogical combinations (e.g. active drug product combined with nutritional supplement), kits containing non-drug items (e.g. antibacterial ointment packaged with bandages) or very expensive dosage forms where inexpensive alternatives exist, that these items be temporarily blocked and brought to the DUR Board on a periodic basis for approval of permanent block or a decision to unblock.

Public Comment: No public comment.

Board Decision: The Board approved as recommended.

9. RetroDUR: *Diane Neal, R.Ph, (MHP)*

Deferred until next meeting due to time constraints.

10. Updated New-to-Market Monitoring Log: *Diane Neal, R.Ph, (MHP)*

- This log shows new entries in the market highlighted in red. The log is informational only. Suggested dates for review are to be used as a guide only. The actual date of review will depend on the complexity of the agenda.

Public Comment: No public comment.

Board Decision: None needed.

11. General Announcements: *Diane Neal, R.Ph, (MHP)*

- Avandia®: There has been much recent controversy surrounding the cardiovascular side effects of Avandia®. The recommendation to the DUR Board is that no changes be made to the PDL at this time and that the controversy be followed for further developments.

Public Comment: Paul Amato, GlaxoSmithKline – Commented on the safety profile of Avandia®.

Board Decision: The Board approved all MHP recommendations.

12. Adjourn: Meeting adjourned at 9:13 p.m.

Next DUR Board Meeting
Tuesday, September 11, 2007
7:00 - 9:00 p.m.*
EDS Building, OVHA Conference Room
312 Hurricane Lane, Williston, VT
(Entrance is in the rear of the building)

* The Board meeting will begin at 6:30 p.m. and the Board will vote to adjourn to Executive Session to discuss Medicaid OBRA'90/Supplemental Rebates and Agreements as provided by 33 VSA § 1998(f)(2). The Executive Session is closed to the public.